Complete Summary

GUIDELINE TITLE

Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome.

BIBLIOGRAPHIC SOURCE(S)

Standards of Practice Committee. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002; 25(2):143-7. [29 references]

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Obstructive sleep apnea syndrome

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Treatment

CLINICAL SPECIALTY

Dentistry
Internal Medicine
Neurology
Otolaryngology
Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dentists
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To present recommendations for using auto-titrating continuous positive airway pressure (APAP) to determine or provide treatment for obstructive sleep apnea

TARGET POPULATION

Adults with obstructive sleep apnea syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Use of standard (i.e., fixed) continuous positive airway pressure (CPAP) (titration and treatment)
- 2. Use of auto-titrating continuous positive airway pressure (APAP) titration and treatment
- 3. Follow-up of patients to determine effectiveness and safety of treatment

MAJOR OUTCOMES CONSIDERED

- Occurrence of sleep apnea or hypopnea, as measured by the apnea plus hypopnea index
- Snoring rates
- Respiratory effort-related sleep arousals
- Mask fit/mask leaks
- Patient comfort, acceptance and utilization rates
- Sleep quality, as measured by amount of slow-wave and REM sleep and arousal index
- Daytime sleepiness
- Occurrence of arterial oxygen desaturation
- Determination of optimal continuous positive airway pressure (CPAP)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search (Medline and EMBASE 1980-June 2001) for articles on treatment with auto-titrating continuous positive airway pressure (APAP) was conducted. Key words for searches included autoCPAP, automatic CPAP, autotitrating CPAP, self-titrating CPAP, self CPAP, autoset, auto PAP, and autoadjusting CPAP. Each search was run separately and findings were then merged. When the search was limited to articles published in English, a total of 55 articles were identified. The set of articles was further reduced to include only those with a major focus on treatment that were published in peer reviewed journals. Studies with a major focus on treatment were defined as: (1) those determining autotitrating positive airway pressure efficacy either as chronic treatment or as a means for determining an optimum pressure for fixed continuous positive airway pressure treatment, or (2) those determining the effect of auto-titrating positive airway pressure on positive pressure acceptance and or adherence. Several reviews, editorials, and articles appearing in journal supplements were included in the references; however these were not used to form conclusions.

NUMBER OF SOURCE DOCUMENTS

This guideline is based on a review of 30 articles published in peer reviewed journals.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Recommendation Grades

A (Evidence Level I)

Randomized well-designed trials with low-alpha & low-beta errors*

B (Evidence Level II)

Randomized trials with high-beta errors*

C (Evidence Level III)

Nonrandomized controlled or concurrent cohort studies

C (Evidence Level IV)

Nonrandomized historical cohort studies

C (Evidence Level V)

Case series

* Alpha error refers to the probability (generally set at 95% or greater) that a significant result (e.g., p < 0.05) is the correct conclusion of the study or studies. Beta error refers to the probability (generally set at 80% or 90% or greater) that a nonsignificant result (e.g., p > 0.05) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis which projects the size of the study population necessary to ensure that significant differences will be observed if actually present.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Thirty articles were selected for inclusion in the evidence tables. Two task force members analyzed each article for design, inclusion and exclusion criteria, outcome measures, biases, and conclusions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When scientific data were insufficient or inconclusive, recommendations were based on consensus opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendation

Standard

 This is a generally accepted patient-care strategy which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline

 This is a patient-care strategy which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option

• This is a patient-care strategy which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved by the Board of Directors of the American Academy of Sleep Medicine.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence levels (I-IV) and the levels of recommendations (standard, guideline, option) are defined at the end of the "Major Recommendations" field.

- 1. A diagnosis of obstructive sleep apnea (OSA) must be established by an acceptable method. (Standard)
- 2. Patients with the following conditions are not currently candidates for autotitrating positive airway pressure (APAP) titration or treatment. (Berry, et al., 2002; sections 5.5, 5.8, and Table 1) (Standard):
 - congestive heart failure
 - lung disease such as chronic obstructive pulmonary disease
 - patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome)
 - patients who do not snore (either due to palate surgery or naturally) should not be titrated with an APAP device that relies on vibration or sound in the device's algorithm.
- 3. APAP devices are not currently recommended for splitnight titration. (Standard)
- 4. Certain APAP devices may be used during attended titration to identify by polysomnography, a single pressure for use with standard continuous positive airway pressure (CPAP) for treatment of OSA. (Berry, et al., 2002; sections 4.0, 5.1, 5.2, 5.3, 5.6, and Table 1) (Guideline)
- 5. Once an initial successful attended CPAP or APAP titration has been determined by polysomnography, certain APAP devices may be used in the self-adjusting mode for unattended treatment of patients with OSA. (Berry, et al., 2002; sections 4.0, 5.2, 5.3, 5.6, 5.7, and Table 1) (Guideline)

- 6. Use of unattended APAP to either initially determine pressures for fixed CPAP or for self-adjusting APAP treatment in CPAP-naïve patients is not currently established. (Berry, et al., 2002; sections 5.1, 5.7, and Table 1) (Option)
- 7. Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must be followed to determine treatment effectiveness and safety. (Standard)
- 8. A re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or the CPAP or APAP treatment otherwise appears to lack efficacy. (Standard)

Definitions:

Evidence Levels:

- I. Randomized, well-designed trials with low alpha and beta error
- II. Randomized trials with high alpha and beta error
- III. Nonrandomized concurrently controlled studies
- IV. Nonrandomized historically controlled studies
- V. Case series

Levels of Recommendations:

Standard - This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline - This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option - This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS.

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

In most cases the conclusions are based on evidence from controlled studies published in peer reviewed journals. Due to overlap with other topics, references are also made to prior American Academy of Sleep Medicine practice parameters. It is indicated when scientific data are insufficient or inconclusive. In such cases, consensus opinion may be used to support the available evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- In general, the guidelines offer an evaluation of auto-titrating continuous positive airway pressure that may assist clinicians in making a more informed decision on its use in the treatment of obstructive sleep apnea.
- One potential use of auto-titrating continuous positive airway pressure is to identify a single pressure for use with a standard continuous positive airway device for subsequent treatment of obstructive sleep apnea. Based on Level I and II and Grade A and B evidence, auto-titrating continuous positive airway pressure devices using methods that involve snoring, apnea or hypopnea monitoring by airflow, airflow against time, or impedance by the forced oscillation technique may effectively determine a pressure to reduce sleep-disordered breathing events to the same extent as standard continuous positive airway pressure titration. Current Level I and II and Grade A and B evidence is specific to each device, including current software and device version. Some devices have not been fully tested in Level I and Level II trials. Caution should be exercised in selecting a particular device for use. Titration is attended in these studies so that issues such as mask fit, pressure leak, and occurrences of transient hypoxemia can be identified and properly managed.
- Another potential use of auto-titrating continuous positive airway pressure is to treat patients with obstructive sleep apnea on a long-term basis. Based on Level I and II and Grade A and B evidence, auto-titrating continuous positive airway pressure devices using methods that involve snoring, apnea or hypopnea monitoring by airflow, airflow against time, or impedance by the forced oscillation technique may effectively adjust pressures to reduce sleep-disordered breathing events to the same extent as standard continuous positive airway pressure titration. Current Level I and II and Grade A and B evidence is specific to each device, including current software and device version. Caution should be exercised in selecting a particular device for use. Since the initial continuous positive airway pressure or auto-titrating continuous positive airway pressure titration is attended, other issues such as mask fit, mask leak, and transient hypoxemia can be identified and managed at the time of titration.

POTENTIAL HARMS

- Central apnea during auto-titrating positive airway pressure treatment or titration may occur in some patients.
- Pressure intolerance can occur with continuous positive airway pressure, along with nasal congestion and dryness.
- Many sleep physicians have encountered patients with intact airflow on continuous positive airway pressure who have persistent oxyhemoglobin

- desaturation during rapid eye movement sleep, presumably secondary to hypoventilation.
- Mask/mouth leaks may lead to problems using auto-titrating positive airway pressure devices.

Subgroups Most Likely to be Harmed:

Patients with lung disease and obstructive sleep apnea, or obesity hypoventilation syndrome might also potentially have problems during unattended auto-titrating positive airway pressure titrations. These patients can desaturate during sleep in the absence of apnea or hypopnea, especially during rapid eye movement sleep.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The intent here is to present the evidence for auto-titrating positive airway pressure's (APAPs) utility, not to make direct treatment recommendations. Nonetheless, the American Academy of Sleep Medicine recognizes this information may affect treatment decisions. The American Academy of Sleep Medicine has previously published practice parameters for the diagnosis of obstructive sleep apnea (OSA) and the recommendations here do not modify those guidelines. The American Academy of Sleep Medicine also has previously published practice parameters on the determination of continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea. The recommendations here add to those previous guidelines when auto-titrating positive airway pressure is used to titrate continuous positive airway pressure or treat obstructive sleep apnea.
- There were several factors complicating the analysis. First, there are many different devices and findings from one device may not extrapolate to others. Second, many of the studies were clinical series in which use of the device was shown to be clinically feasible and effective but not compared to conventional continuous positive airway pressure treatment or placebo. The entry criteria were not always clearly stated so that in some studies there may have been a selection bias. Third, even when randomized controlled trials were performed, the designs varied significantly.
- These practice parameters define principles of practice that should meet the needs of most patients in most situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding propriety of any specific care must be made by the physician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Standards of Practice Committee. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002; 25(2):143-7. [29 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 March 15

GUI DELI NE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Standards of Practice Committee: Michael Littner MD; Maxwell Hirshkowitz PhD; David Davila MD; W. McDowell Anderson MD; Clete A. Kushida MD, PhD; B. Tucker Woodson MD, FACS; Stephen F. Johnson MD; and Merrill S. Wise MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the American Academy of Sleep Medicine's Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine Web site.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: http://www.aasmnet.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. An American Academy of Sleep Medicine review. Sleep. 2002 Mar 15;25(2):148-73.

Electronic copies: Available in Portable Document Format (PDF) from the <u>American Academy of Sleep Medicine Web site</u>.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: http://www.aasmnet.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 19, 2002. The information was verified by the guideline developer on September 13, 2002.

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Date Modified: 11/8/2004

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